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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,021	12/02/2003	Timothy W. Lovenberg	JPR-0043	5495
23377 7590 12/13/2005				
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103				
EXAMINER HAMUD, FOZIA M				
ART UNIT		PAPER NUMBER		
1647				

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/727,021

Applicant(s)

LOVENBERG ET AL.

Examiner

Fozia M. Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,25,27,28,34-36 and 40-54 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 24-25, 27-28, 34-36, 38, 40-54 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Response to Amendment

1a. Receipt of Applicants' amendment and arguments filed on 05 October 2005 is acknowledged.

Status of Claims:

1b. Claims 1-23, 26, 29-33, 37, 39 have been cancelled and new claims 41-54 have been added. Thus, claims 24, 25, 27-28, 34-36, 38 and 40-54 are pending, and under consideration.

1c. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 10/05/2005.

(I) All of the rejections of cancelled claims 26, 29-33, 37 and 39 are moot.

(II) The rejection of claims 24, 27, 34-36, 38 and 40 made under 35 U.S.C. 12, first paragraph, for not complying with the written description provision of this statute is withdrawn, because these claims now recite appropriate sequences.

(III) The rejection of claims 24, 26, 27, 36, 38 and 40 made under 35 U.S.C. 12, first paragraph, for not enabling the full scope of the claimed invention, is withdrawn, because these claims now recite appropriate sequences.

(IV) The rejection of claims 24-36, 38 and 40, made under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn. Applicants' argument that one skilled in the art would understand the hybridization conditions under which homologues of human

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histamine H3 receptor could be identified using DNA that encoded the polypeptide of SEQ ID NO:7, is found persuasive.

(V). The rejection of claims 24, 27 made under 35 U.S.C § 102(e) as being anticipated by U.S Patent No: 5,882,893 (Goodearl et al. published 16 March 1999; effective filing date 04 December 1997), is withdrawn. The Goodearl et al reference does not disclose a method of using a nucleic acid encoding the polypeptide of SEQ ID NO:7, to isolate DNA encoding a homologue of human histamine H3 receptor, and isolating homologue of human H3 receptor that retains the biological activity of the polypeptide of SEQ ID NO:7.

New Rejections:

3a. Claims 24, 27, 34-35, 38, 40 and 53-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using a nucleic acid encoding the polypeptide of SEQ ID NO:7 to isolate or produce a homologue of human histamine H3 receptor that binds to the specific ligands recited on claims 36, 42, 46, 50 and exhibit the biological activities recited on claims 41, 43-45, 47-51, does not enable a method isolating or producing a homologue of human histamine H3 receptor that has greater or reduced affinity for "all possible" ligands, than the human histamine receptor H3 of SEQ ID NO:7, or exhibit "all possible" biological activities of the human histamine receptor H3 of SEQ ID NO:7.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

With respect to the recitation of "biological activity" in the claims, Applicants' argument that the specification teaches how to identify said activities, is not found persuasive, because Applicants are arguing limitations not recited in the claims. Applicants are correct that the specification discloses how to monitor or identify histamine H3 receptor activities, and new claims 41, 43-45, 47-51 recite said specific activities. However, claims 24, 27, 38, 40 and 54 encompass "all possible biological activities". Regarding claims 34 and 35, the recitation of "a ligand", encompasses "all possible ligands", while the specification discloses specific ligands for the polypeptide of SEQ ID NO:7. Claims 36, 42, 46, 50, recite specific ligands for the polypeptide of SEQ ID N:7. Therefore, due to the lack of direction/guidance presented in the specification regarding "all possible ligands" and "all possible biological activities", the complex nature of the invention, and the breadth of the claims, which fail to recite particular biological activities, undue experimentation would be required of the skilled artisan to practice the claimed invention in its full scope. In the absence of more guidance, one skilled in the art would have to proceed with undue trial and error experimentation to screen through a vast number of ligands to identify homologues of human histamine H3 receptor that retain the desired specific biological of SEQ ID NO: 7.

Claim Rejections - 35 U.S.C. § 112, second paragraph:

4. Claims 24-25, 27-28, 34-36, 38 and 40-54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4a. Claims 24, 25, 27, 28, 38, and 40, recite the article "an or a" when referring to a specific polypeptide or nucleic acid. For example, claim 24 recites in line 4 and line 13 "...**an** amino acid sequence of SEQ ID NO:7....", however, this renders the claim vague and indefinite, because it is unclear whether only part of the polypeptide of SEQ ID NO:7 is being referred to. Likewise, claim 24, sub-part (b) recites "...encoding **a** human histamine receptor...", although this section of the claim is referring to specific one. It is suggested that the claims be amended to recite the article "**the**", when referring to a specific sequence, for example ".....the amino acid sequence of SEQ ID NO:7....". Appropriate correction is required.

Claims 34, 35, 36, 41-54 are rejected in so far as they depend on claims 24, 27, 38 or 40 for the limitations set forth above.

Conclusion:

5. No claim is allowed.

The claims are free of the prior art of record.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
08 December 2005


JOSEPH MURPHY
PATENT EXAMINER



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
Covenberg et al.

Confirmation No.: **5495**Application No.: **10/727,021**Group Art Unit: **1647**Filing Date: **December 2, 2003**Examiner: **Fozia M. Hamud**For: **DNA Encoding A Human Histamine Receptor Of The H3 Subtype**

DATE OF DEPOSIT: September 27, 2005

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DEPOSITED WITH THE UNITED STATES POSTAL
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TYPED NAME: Felicity B. Groth
REGISTRATION NO.: 47,042

☒ MS Amendment ☐ MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY TRANSMITTAL LETTER

- ☐ A Preliminary Amendment.
- ☒ A Reply Responsive to the Office Action Dated June 27, 2005.
- ☐ A Reply Supplemental to the Paper filed
- ☐ A Substitute Specification (pages 1 -) in clean form.
- ☐ A substitute specification (pages 1 -) with markings.
- ☐ An Abstract is enclosed.
- ☐ replacement sheets of drawings are enclosed comprising figures
- ☐ Request is hereby made to accept black and white photograph(s) in this case, as they are the only practicable medium for illustrating the claimed invention. One (1) set of black and white photographs comprising figure(s) is submitted herewith.


- ☐ Petition is hereby made to accept drawing(s)/photograph(s) in this case.
- ☐ Three (3) sets of color drawing(s)/photograph(s) and black and white photocopy that accurately depicts to the extent possible, the subject matter shown in the color drawing(s)/photograph(s), are enclosed, comprising figures
- ☐ An amendment to the first paragraph in that portion of the Brief Description of the Drawings is also enclosed herewith advising that the patent contains at least one drawing/photograph in color.
- ☐ A Certified Copy of each of the following applications: is enclosed.
- ☐ An Assignee Power of Attorney is enclosed.
- ☐ Information Disclosure Statement.
- ☐ Attached Form 1449.
- ☐ A copy of each reference as listed on the attached Form PTO-1449 is enclosed herewith.
- ☐ A Terminal Disclaimer is attached.
- ☐ Appendices as follows:
- ☐ Other
- ☒ **No Additional Fee is Due.**
- ☐ Applicant(s) has previously claimed small entity status under 37 CFR § 1.27.
- ☐ Applicant(s) by its/their undersigned attorney, claims small entity status under 37 CFR § 1.27 as
- ☐ This application is no longer entitled to small entity status. It is requested that this be noted in the files of the U.S. Patent and Trademark Office.

				SMALL ENTITY		NOT SMALL ENTITY	
	REMAINING AFTER AMENDMENT	HIGHEST PAID FOR	EXTRA	RATE	FEE	RATE	FEE
TOTAL CLAIMS	19	19 (20 MINIMUM)	0	\$25 EACH	\$	\$50 EACH	\$0
INDEP. CLAIMS	4	6 (3 MINIMUM)	0	\$100 EACH	\$	\$200 EACH	\$0
FIRST PRESENTATION OF MULTIPLE DEPENDENT				\$180	\$	\$360	\$0
<input type="checkbox"/> ONE MONTH EXTENSION OF TIME				\$60	\$	\$120	\$0
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<input type="checkbox"/> LESS ANY EXTENSION FEE ALREADY PAID				minus	(\$)	minus	(\$0)
<input type="checkbox"/> TERMINAL DISCLAIMER				\$65	\$	\$130	\$0
<input type="checkbox"/> OTHER FEE OR SURCHARGE AS FOLLOWS:							
TOTAL FEE DUE					\$		\$0

- ☐ A check in the amount of \$.00 is attached. Please charge any deficiency or credit any overpayment to Deposit Account 23-3050.
- ☐ Please charge Deposit Account No. 23-3050 in the amount of .00. This sheet is attached in duplicate.
- ☒ The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 23-3050.
- ☐ Petition is hereby made under 37 CFR § 1.136(a) (fees: 37 CFR § 1.17(a)(1)-(4)) to extend the time for response to the Office Action of _____ to and through _____ comprising an extension of the shortened statutory period of _____ month(s).

- ☒ The Commissioner is hereby requested to grant an extension of time for the appropriate length of time, should one be necessary, in connection with this filing or any future filing submitted to the U.S. Patent and Trademark Office in the above-identified application during the pendency of this application. The Commissioner is further authorized to charge any fees related to any such extension of time to Deposit Account 23-3050. This sheet is provided in duplicate.

Date: September 27, 2005



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Lovenberg et al.

Confirmation No.: 5495

Application No.: 10/727,021

Group Art Unit: 1647

Filing Date: December 2, 2003

Examiner: Fozia M. Hamud

For: DNA Encoding A Human Histamine Receptor of the H3 Subtype

DATE OF DEPOSIT: September 27, 2005

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.


(TYPED NAME: Felicity E. Groth
REGISTRATION NO.: 47,042

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY PURSUANT TO 37 CFR § 1.111

In response to the Official Action dated **June 27, 2005**, reconsideration is respectfully requested in view of the amendments and/or remarks as indicated below:

- ☒ **Amendments to the Specification** begin on page 2 of this paper.
- ☒ **Amendments to the Claims** are reflected in the listing of the claims which begins on page 3 of this paper.
- ☐ **Amendments to the Drawings** begin on page _____ of this paper and include an attached replacement sheet.
- ☒ **Remarks** begin on page 7 of this paper.

Amendments to the Specification:

Please amend the title to read as follows:

“Methods of Use of DNA Encoding a Human Histamine Receptor of the H3
Subtype.”

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1-23. (Canceled)

24. (Currently amended) A method for isolating DNA a nucleic acid molecule encoding a homologue of human histamine H3 receptor comprising the steps of:

(a) mixing a nucleic acid molecule encoding human histamine H3 receptor DNA comprising an amino acid sequence of SEQ ID NO:7 with a sample comprising a nucleic acid molecule DNA encoding a homologue of human histamine H3 receptor;

(b) allowing said nucleic acid molecule encoding a human histamine H3 receptor DNA to hybridize with said nucleic acid molecule DNA encoding a homologue of human histamine H3 receptor to form a hybridized nucleic acid DNA complex;

(c) isolating the hybridized nucleic acid DNA complex; and

(d) purifying the nucleic acid molecule DNA encoding a human histamine H3 receptor homologue,

wherein said histamine H3 receptor homologue comprises biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7.

25. (Currently amended) The method according to claim 24 wherein said nucleic acid molecule encoding human histamine H3 receptor DNA has a nucleotide sequence of SEQ ID NO:5 or SEQ ID NO:6.

26. (Canceled)

27. (Currently amended) A method for producing a homologue of human histamine H3 receptor comprising the steps of:

(a) mixing a nucleic acid molecule encoding human histamine H3 receptor DNA comprising an amino acid sequence of SEQ ID NO:7 with a sample comprising a nucleic acid molecule DNA encoding a homologue of human histamine H3 receptor;

(b) allowing said nucleic acid molecule encoding human histamine H3 receptor DNA to hybridize with said nucleic acid molecule DNA encoding a homologue of human histamine H3 receptor to form a hybridized nucleic acid DNA-complex;

(c) isolating the hybridized nucleic acid DNA-complex; and

(d) purifying the nucleic acid molecule ~~DNA~~ encoding a human histamine H3 receptor homologue; and

(e) recombinantly expressing said nucleic acid molecule ~~DNA~~ encoding a human histamine H3 receptor homologue,

thereby producing said human histamine H3 receptor homologue, wherein said histamine H3 receptor homologue comprises biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7.

28. (Currently amended) The method according to claim 27 wherein said nucleic acid molecule encoding human histamine H3 receptor ~~DNA~~ has a nucleotide sequence of SEQ ID NO:5 or SEQ ID NO:6.

29-33. (Canceled)

34. (Previously presented) The method according to claim 27 wherein said homologue has a greater affinity for a ligand than the polypeptide having an amino acid sequence of SEQ ID NO:7.

35. (Previously presented) The method according to claim 27 wherein said homologue has a reduced affinity for a ligand than the polypeptide having an amino acid sequence of SEQ ID NO:7.

36. (Previously presented) The method according to claim 34 or 35 wherein said ligand is histamine or methylhistamine.

37. (Canceled)

38. (Currently amended) A method for detecting the presence of a nucleic acid molecule encoding a human histamine H3 receptor ~~DNA~~ in a sample comprising nucleic acid molecules ~~acids~~, said method comprising the steps of:

(a) mixing said sample with a nucleic acid molecule having a nucleotide sequence of SEQ ID NO:5, a nucleotide sequence of SEQ ID NO:6, a nucleotide sequence of SEQ ID NO:8, or a nucleotide sequence encoding SEQ ID NO:7, or a fragment thereof, and

(b) detecting hybridization of said nucleic acid molecule to a nucleic acid molecule in said sample,

wherein said nucleic acid molecule encoding a human histamine H3 receptor comprises biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7.

39. (Canceled)

40. (Currently amended) A kit for detecting the presence of a nucleic acid molecule encoding a human histamine H3 receptor DNA, wherein said nucleic acid molecule comprises a nucleic acid sequence comprising a nucleic acid molecule of SEQ ID NO:5, 6, or 8, or wherein said human histamine H3 receptor comprises an a-nucleic acid-molecule encoding the amino acid sequence of SEQ ID NO:7, wherein said nucleic acid molecule encoding a human histamine H3 receptor comprises biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7 or a fragment thereof, and optionally a container.

41. (New) The method of claim 24 wherein said biological activity is binding to a histamine H3 receptor-specific ligand.

42. (New) The method of claim 41 wherein said ligand is thioperamide or alpha-methylhistamine.

43. (New) The method of claim 24 wherein said biological activity is inhibition of adenylyate cyclase in response to histamine.

44. (New) The method of claim 24 wherein said biological activity is incorporation of GTP-gamma-S.

45. (New) The method of claim 27 wherein said biological activity is binding to a histamine H3 receptor-specific ligand.

46. (New) The method of claim 45 wherein said ligand is thioperamide or alpha-methylhistamine.

47. (New) The method of claim 27 wherein said biological activity is inhibition of adenylyate cyclase in response to histamine.

48. (New) The method of claim 27 wherein said biological activity is incorporation of GTP-gamma-S.

49. (New) The method of claim 38 wherein said biological activity is binding to a histamine H3 receptor-specific ligand.

50. (New) The method of claim 49 wherein said ligand is thioperamide or alpha-methylhistamine.

51. (New) The method of claim 38 wherein said biological activity is inhibition of adenylyate cyclase in response to histamine.

52. (New) The method of claim 38 wherein said biological activity is incorporation of GTP-gamma-S.

53. (New) The kit of claim 40 further comprising a means for detecting said biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7

54. (New) The kit of claim 53 wherein said means is a histamine H3 receptor-specific ligand.

REMARKS

Upon entry of this amendment, claims 24, 25, 27, 28, 34-36, 38, and 40-54 will be pending in the application. Claims 24, 25, 27, 28, 38, and 40 are amended to recite nucleic acid molecules, as supported throughout the specification, for example, at page 4. Claims 24 and 27 are amended to recite nucleic acid molecules encoding human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7, as supported by Figure 3 of the specification. Claims 24, 27, 38, and 40 are amended to recite histamine H3 receptor homologues comprising biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7, as supported at pages 5-6 of the specification. Claims 38 and 40 are amended to omit recitation of the term "fragment." Claims 26, 29-33, 37, and 39 are canceled. Claims 41-54 are added as supported in the specification at pages 3-4. The title has been amended. No new matter is introduced by this amendment.

The withdrawn claims are canceled.

Withdrawn claims 37 and 39 are canceled in view of the finality of the restriction requirement. Applicants reserve the right to pursue the nonelected subject matter at a later date.

The objection to the specification should be withdrawn.

The title of the specification has been amended to "Methods of Use of DNA Encoding a Human Histamine Receptor of the H3 Subtype." Withdrawal of the objection to the specification is respectfully requested.

Claims 24, 27, 34-36, 38, and 40 satisfy the written description requirement.

Claims 24, 26, 27, 29-36, 38, and 40 are rejected under the first paragraph of 35 U.S.C. § 112 for alleged lack of written description. Claims 26 and 29-33 have been canceled. Applicants respectfully note that canceled claim 26 did not recite a fragment. Although Applicants disagree with the rejection, in an effort to advance prosecution of the application, claims 24 and 27 have been amended to recite human histamine H3 receptor of

SEQ ID NO:7, and claims 38 and 40 have been amended to omit reference to a fragment. Withdrawal of the rejection is thus respectfully requested.

Claims 24, 27, 34-36, 38, and 40 are enabled.

Claims 24, 26, 27, 29-36, 38, and 40 are rejected under the first paragraph of 35 U.S.C. § 112 for alleged lack of enablement. Although Applicants disagree with the rejection, claims 24, 27, 38, and 40 have been amended to overcome the rejection.

To the extent the rejection is applied to the amended claims, Applicants traverse. One of ordinary skill in the art at the time of the invention would have been able to make and use all nucleic acid molecules encoding a human histamine H3 receptor having an amino acid sequence of SEQ ID NO:7 in the presently claimed methods without undue experimentation. The genetic code is based on correlation between amino acids and encoding codons such that identification of the amino acid sequence of a protein automatically puts one in possession of all nucleic acid sequences encoding that protein. As acknowledged by the Federal Circuit, "the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it." *In re Wallach*, 378 F.3d 1330, 1333, 71 U.S.P.Q.2d 1939 (Fed. Cir. 2004).

Additionally, one of ordinary skill in the art would have been able to identify homologues having the recited function of human histamine H3 receptor activity without undue experimentation in view of the teachings of the present specification and the knowledge in the art. For example, the specification teaches that human histamine H3 receptor activity can be monitored by performing a ³H-alpha-methylhistamine binding assay known in the art. (Specification, page 4.) The specification also teaches that thioperamide and alpha-methylhistamine are human histamine H3 receptor ligands. (Specification, page 3.) Additionally, it is taught in the specification that H3 histamine receptor activity can be measured by inhibition of adenylate cyclase in response to histamine or incorporation of GTP-gamma-S. (Specification, page 4.) One of ordinary skill in the art would have been able to use the methods of the invention to arrive at human histamine H3 receptor homologues with nothing more than routine experimentation.

Withdrawal of the rejection is thus respectfully requested.

Claims 24, 27, 38, and 40 comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph.

Claims 24, 27, 30, 38, and 40 are rejected for alleged failure to comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph. Claim 30 has been canceled.

Claim 24, 27, 38, and 40 are rejected for alleged failure to recite specific hybridization conditions. Applicants respectfully assert that one skilled in the art would understand the hybridization conditions under which homologues of human histamine H3 receptor, including species homologues, could be identified in view of the knowledge in the art. Nonetheless, in an effort to advance prosecution of the application, Applicants have amended the claims to recite a histamine H3 receptor homologue having a biological activity of a human histamine H3 receptor having an amino acid sequence of SEQ ID NO:7. Withdrawal of the rejection is thus respectfully requested.

Claims 24 and 27 are patentable over U.S. Patent No. 5,882,893.

Claims 24 and 27 are rejected under 35 U.S.C. § 102(e) for alleged anticipation by U.S. Patent No. 5,882,983 to Goodearl *et al.* Although Applicants disagree with the rejection, in an effort to advance prosecution of the application, Applicants have amended the claims to recite histamine H3 receptor homologues comprising biological activity of a human histamine H3 receptor comprising an amino acid sequence of SEQ ID NO:7, as supported at pages 5-6 of the specification. As the record fails to establish that the cited reference teaches each limitation of the presently claimed invention, withdrawal of the rejection is respectfully requested.


CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the undersigned may be contacted at 215-557-5908.

Respectfully submitted,

Date: September 27, 2005



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